

## ASHBY & GEDDES

ATTORNEYS AND COUNSELLORS AT LAW  
222 DELAWARE AVENUE  
P. O. BOX 1150  
WILMINGTON, DELAWARE 19899

TELEPHONE  
302-654-1888  
FACSIMILE  
302-654-2067

August 26, 2005

The Honorable Gregory M. Sleet  
United States District Court  
844 N. King Street  
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: *Abbott Diabetes Care, Inc. v. DexCom, Inc.*,  
C.A. No. 05-590-GMS

Dear Judge Sleet:

I am Delaware counsel to the defendant in the above action, DexCom, Inc. ("DexCom"), whose response to the complaint is due on August 31, 2005. Although we do not believe that our planned response is inconsistent with Your Honor's standard procedures, out of an abundance of caution, and as a courtesy to the Court, we thought it best to alert the Court as to how we plan to proceed.

Plaintiff, Abbott Diabetes Care, Inc. ("Abbott"), filed this action on August 11, 2005. The Complaint seeks a declaration that DexCom's continuous glucose monitoring system ("STS") for persons with diabetes – which is still being evaluated and reviewed by the Food and Drug Administration ("FDA"), which is not yet being marketed, and which is not yet commercially available – infringes unspecified claims of four United States patents which Abbott acquired recently. The Complaint also alleges that DexCom's display at two diabetes-related scientific conferences (including the ADA's June 2005 "65th Annual Scientific Sessions") constitutes infringement of the four asserted patents.

DexCom intends to file a motion to dismiss Abbott's Complaint on several grounds. First, DexCom's STS system is still undergoing scientific and regulatory review by the FDA for safety and efficacy, and there is no guarantee that the FDA will approve the STS system at all. Even if the FDA does approve the STS system, the FDA may require that DexCom change the device and the way it will operate. Abbott's anticipated dispute with DexCom is not ripe at this stage of the FDA review process, given that, in a patent infringement lawsuit, the Court must compare the accused device with the construed claims of the asserted patents. Since whether, and in what form, the actual accused device will exist is still unknown at this stage, Abbott's lawsuit is premature. Similarly, DexCom's attendance at the two "trade shows" falls within the

The Honorable Gregory M. Sleet  
August 26, 2005  
Page 2

statutory exception to patent infringement under 35 U.S.C. § 271(e)(1), as interpreted by the Federal Circuit. Finally, DexCom's STS has never been commercially marketed or made available. It has only been made available to physicians, pursuant to confidentiality agreements, in limited clinical trials under strictly controlled FDA guidelines where each system must be closely tracked and accounted for. Thus, Abbott could not have obtained an STS system in order to conduct the pre-suit investigation mandated under Rule 11 and Federal Circuit precedent.

DexCom's motion to dismiss will rely not only upon Abbott's Complaint, but also upon matters outside the Complaint of which the Court properly can take judicial notice. What prompts this letter is our awareness of the fact that Your Honor requires leave of Court to file summary judgment motions. Although DexCom's motion will be a threshold motion to dismiss under Rule 12, and will not be a motion for summary judgment under Rule 56, it will be supported by facts outside of the pleadings. We therefore write in advance, just in case the Court considers our intended filing to come within the spirit, even though not the letter, of Your Honor's summary judgment procedure. If Your Honor has any such concerns, we would be pleased to address them and seek the Court's guidance, either during a teleconference or in whatever other fashion the Court prefers.

Respectfully,

*/s/ Steven J. Balick*

Steven J. Balick

SJB/dmf  
160796.1

cc: Mary B. Graham, Esq. (by hand)  
James F. Hurst, Esq. (via facsimile)  
David C. Doyle, Esq. (via facsimile)